AWARD NUMBER: W81XWH-15-1-0154

TITLE: Efficacy of the Direct Instruction Language for Learning (DI-LL) Program to Promote Expressive and Receptive Language in Children with Autism Spectrum Disorder

PRINCIPAL INVESTIGATOR: Lawrence Scahill, MSN, PhD

CONTRACTING ORGANIZATION: Emory University
Atlanta, GA 30322

REPORT DATE: July 2016

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
July 2016	Annual	15Jun2015 - 14Jun2016

4. TITLE AND SUBTITLE

"Efficacy of the Direct Instruction Language for Learning (DI-LL) Program to Promote Expressive and Receptive Language in Children with Autism Spectrum Disorder"

5a. CONTRACT NUMBER
W81XWH-15-1-0154

5b. GRANT NUMBER
W81XWH-15-1-0154

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

Scahill, Lawrence, MSN, PhD, Shillingsberg, M Alice, PhD, Bowen, Crystal, MS, Badura, Marc, MS

E-Mail: marc.badura@choa.org; lawrence.scahill@emory.edu

5d. PROJECT NUMBER
10685862

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Emory University
1920 Briarcliff Rd
Atlanta, GA 30329

8. PERFORMING ORGANIZATION REPORT NUMBER

None

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)
eIRB

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

None

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

Nothing to report

14. ABSTRACT

Available information indicates that as many as 75% of children with autism spectrum disorder (ASD) have language delay ranging from mild to severe. Many interventions have been developed to address language delay including intensive treatment using applied behavior analysis (ABA). Although often effective for severe language delay (e.g., children with no language), intensive ABA intervention may not be needed for children with moderate language delay. Untreated moderate language delay predictably interferes with the child's ability to advance in the social and academic domains. Direct Instruction – Language for Learning (DI-LL) is a highly structured intervention with empirical support in children with language delay uncomplicated by autism spectrum disorder. However, DI-LL has not yet been carefully studied in children with ASD. As in ABA, the DI-LL curriculum incorporates immediate reinforcement for correct responses, immediate and systematic error correction procedures, shaping, prompting, and fading. To date, there is only one small study of DI-LL in children with ASD and language delay. The purpose of this study is to test the efficacy of DI-LL in a six-month randomized trial in 100 children with ASD and moderate language delay. Eligible subjects will be randomly assigned to DI-LL or Treatment As Usual (TAU) for 6 months.

15. SUBJECT TERMS

Autism Spectrum Disorder, Language, Communication

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	7	19b. TELEPHONE NUMBER *code)*

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

Table of Contents

1. INTRODUCTION:

Available information indicates that as many as 75% of children with autism spectrum disorder (ASD) have language delay ranging from mild to severe. Many interventions have been developed to address language delay including intensive treatment using applied behavior analysis (ABA). Although often effective for severe language delay (e.g., children with no language), intensive ABA intervention may not be needed for children with moderate language delay. Moderate language delay that is not treated predictably interferes with the child's ability to advance in the social and academic domains. Direct Instruction – Language for Learning (DI-LL) is a highly structured intervention with empirical support in children with language delay uncomplicated by autism spectrum disorder. However, DI-LL has not yet been applied to children with ASD. As in ABA, the DI-LL curriculum incorporates immediate reinforcement for correct responses, immediate and systematic error correction procedures, shaping, prompting, and fading. To date, there is only one small study of DI-LL in children with ASD and language delay. The purpose of this study is to test the efficacy of DI-LL in a six-month randomized trial in 100 children with ASD and moderate language delay. Eligible subjects will be randomly assigned to DI-LL or Treatment As Usual (TAU) for 6 months.

KEYWORDS:

Autism Spectrum Disorder, Language Delay, Communication, Clinical Trial

2. OVERALL PROJECT SUMMARY:

Statement of Work

The following Major Tasks were completed in this year of the grant

Tasks	Month(s) completed
Complete IRB application	1-3
Finalize consent form & human subjects protocol	1-3
Complete regulatory documents (regulatory binder)	1-3
Register study on clinicaltrials.gov	1-3
Train Independent Evaluator on PLP & CGI	1-3
Train staff on DOSL	1-3
Purchase child materials (toys, stickers)	1-3
Purchase testing materials	1-3
Purchase DI-LL program	1-3
Develop recruitment materials	1-3
Complete data base	6
Train Coordinator on data entry system	6
Milestone: IRB approval	3
Milestone: Data base tested and ready	6
Bring on first of three therapists	1-3
Milestone: Randomized first subject	3
Continue Enrollment	Ongoing
Bring on second and third therapists and continue enrollment	6
Continue Enrollment	7-50
Convene DSMB meeting	9

Changes

In the original application and IRB protocol, the change in the Core Language composite on the Clinical Evaluation of Language Fundamentals, 4th edition (CELF-4) was the primary outcome measure. It was selected because it is a reliable, valid and has been used as an outcome measure in prior studies. To be eligible, study participants had to demonstrate an 18-month or greater mental age equivalence on a standard IQ test and < 80 on the Core Language score of the Clinical Evaluation of Language Fundamentals (CELF-4).

We began screening subjects in mid-October 2015. Of the first three subjects, two appeared to be appropriate for the study; one was too severely delayed. The two subjects who appeared appropriate, however, achieved a score of 40. This is the lowest possible score on the CELF-4. For children who achieve a score of 40 on the CELF-4, their true baseline score is unknown and could, in fact, be lower than 40. Thus, although the CELF-4 fits with the age range of the study, some children who otherwise appear to be appropriate for the study score too low on the CELF-4 making it impossible to establish a baseline.

The developers of the CELF-4 have a companion test called the CELF-Preschool (second edition). As with the CELF-4, the CELF-Preschool (CELF-P) has a Core battery that provides a composite standard score (M=100, SD=15). The Core battery on the CELF-P focuses on similar constructs (receptive and expressive language skills and language structure) as the CELF-4. The CELF-4 and CELF-P also have overlapping norms (3 to 6 years 11 months for CELF-Preschool and 5 to 8 years 11 months for CELF-4). The performance requirements for the CELF-P are easier than the CELF-4. Thus, children who cannot achieve a score above 40 on the CELF-4 may be able to achieve a useable baseline score on the CELF-P. NOTE: within the appropriate age range of each test, changes in the standard scores on the CELF-4 and CELF-P are interchangeable.

Therefore, we amended the protocol to accept the change on the Core Language standard score of the CELF-4 or the Core Language standard score on the CELF-P as the primary outcome measure. [NOTE: The test (CELF-4 or CELF-P) given at Week 24 will be the same test that was administered pre-treatment.]

Minor changes to inclusion criteria. 1) The addition of the CELF-P permits us to lower the age range from 5 years to ≤ 7 years 11 months to 4 years to 7 years 11 months of age. We deliberately chose not to go below 4 years of age to avoid the problem of hitting the test floor of 45 on the CELF-P in younger children.
For completeness, we added the CELP-P to the inclusion criteria: 2) Males and females ≥ 4 years and ≤ 7 years 11 months of age in pre-school or elementary school with a score ≤ 80 on the Core battery of the CELF-4 or the CELF-P

Minor change to exclusion criteria. Children > 6 years 5 months who achieve a score of 40 on the CELF-4 will be excluded [Note: The norms for the CELF-P stop at 6 years 11 months. Thus, children who are older than 6 years 5 months at baseline would be older than 6 years 11 months at Week 24. In these children the use of the CELF-P at endpoint would not be an option.]

Problems

We learned that reliance on the CELF-4 would likely result in exclusion of children who might otherwise be appropriate for the study. Because change in the standard score of the CELF-4 and CELF-P are interchangeable, the addition of the CELF-P should obviate this problem.

Participants

To date, parents of 25 children have consented to enroll the child into the study. Nine of 25 subjects failed the screening. Of these, 6 scored too low on the CELF-4 or CELF-P, two subjects did not meet criteria for moderate language delay; one subject exhibited significant disruptive behavior and was excluded; one apparently eligible subject declined to enter. 12 subjects have been randomized; 4 completed the 24-week study.

3. KEY RESEARCH ACCOMPLISHMENTS:

Nothing to report

4. CONCLUSION:

We began active enrollment in October, 2015. We have no results to report at this time. If our study shows that DI-LL is effective for children with ASD and moderate language delay, it has the potential to make an important contribution to the field. DI-LL is a highly structured exportable intervention that can be applied in real world settings delivered by a range of practitioners.

We have completed training of the first study therapist and developed a range of strategies for recruitment. We also hired a coordinator to help with recruitment efforts and study execution.

5. PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS:

(1) Lay Press: None
(2) Peer-Reviewed Scientific Journals: None
(3) Invited Articles: None
(4) Abstracts: None

a. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.

Nothing to report

6. INVENTIONS, PATENTS AND LICENSES:

Nothing to report

7. REPORTABLE OUTCOMES:

Nothing to report

8. OTHER ACHIEVEMENTS:

Nothing to report

9. REFERENCES:

Nothing to report

10. APPENDICES:

Nothing to Report

TRAINING OR FELLOWSHIP AWARDS:
Program is just starting. We expect to include post-doctoral fellows as therapists in the intervention and to learn the direct observation outcomes.

COLLABORATIVE AWARDS:
Nothing to Report

MARKING OF PROPRIETARY INFORMATION:
Nothing to Report